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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/535,314 03/24/00 BRIDGER

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HM12/0327

EXAMINER

BALASUBRAMANIAN, V

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/535,314

Applicant(s)

Bridger et al.

Examiner

Venkataraman Balasubramanian

Group Art Unit

1624



☒ Responsive to communication(s) filed on Feb 15, 2001

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-4, 6, 7, 12, 13, 51, 55-58, 91, 93-106, 108-114, 117, and 118 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-4, 6, 7, 12, 13, 51, 55-58, 91, 93-106, 108-114, 117 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Applicants' preliminary amendment filed on 2/15/01 is made of record Accordingly claims 1-4, 6-7, 12-13, 51, 55-58, 91, 93-106, 108-114 and 117-118 are now pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 6-7, 12-13, 51, 55-58, 94-102, drawn to compound of formula I wherein P in the X variants is a carbon and composition, classified in classes various, subclasses various depending upon the preferred embodiments of Ar- hetero ring substituents.
- II. Claims 1-4, 6-7, 12-13, 51, 55-58, 94-102, drawn to compound of formula I wherein P in the X variants is a nitrogen and composition, classified in class 546 sub classes 152, 346, class 514, sub class 352 and other classes and subclasses depending upon the preferred embodiments of Ar- hetero ring substituents.
- III. Claims 1-4, 6-7, 12-13, 51, 55-58, 94-102, drawn to compound of formula I wherein P in the X variants is a oxygen and composition, classified in class 549, subclass 346, class 514 subclass 456 and other classes and subclasses depending upon the preferred embodiments of Ar- hetero ring substituents.
- IV. Claims 1-4, 6-7, 12-13, 51, 55-58, 94-102, drawn to compound of formula I wherein P in the X variants is a sulfur atom and composition, classified in class 549 subclass

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23, class 514 subclass 432 and other classes and subclasses depending upon the preferred embodiments of Ar- hetero ring substituents.

V. Claims 91 and 93 , drawn to compound of formula I wherein P in the X variants is linked Z or fused to a carbon classified in classes various, subclasses various depending upon the preferred embodiments of X and Ar- hetero ring substituents as noted in group I-IV.

VI. Claims 103-106, 108-114 and 117-118 drawn to multiple method of use of compound of formula 1, classified in class 514, subclass subclasses various depending upon the preferred embodiment of X and Ar- hetero ring substituents as noted in group I-IV.

If any one of the group I-V is elected, applicants may elect a specific method of use from group VI for a specific disease.

The inventions are distinct, each from the other because of the following reasons:

Inventions I through VI are independent and distinct from each other because they are directed to structurally dissimilar compounds that lack common core namely pyridine or quinoline vs pyran or benzopyran vs thiane or benzofused thiane vs benzenoid . Consequently, the groups have different classifications and require separate prior art searches. Search of these class of compounds with variant permitted would pose a serious burden. They can be made and used independently. Art which may render obvious or anticipate one of the groups would not necessarily do the same for the other group. Each can support a patent as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

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Inventions I-V and VI are related as product and multiple method of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compound of claim 1 can be used for treating variety of disease as evidenced by applicants claims. Similarly, it is clear from the claims that the process of using can be practiced with materially different products as evidenced by the prior art provided by the applicants. Furthermore, issues of patentability of invention VI such as 112 issues are distinct from those of compounds of invention of I-V.

The recent utility guidelines set by PTO require applicants to meet the requirements as stated in *Brenner v. Manson* in 148 USPQ 689, which requires that utility be developed to a point where “specific benefits exist in currently available form. Similar is the “immediate benefits to the public” standard that *Nelson v Bowler*, 206 USPQ 880 refers to. The standard set forth in the concurring opinion of the *In re Hartop*, 135 USPQ 419 is whether the invention has been brought to such perfection as to be capable of practical employment. This language is echoed in *Bindra vs Kelly* 206 USPQ 570.

MPEP 806.05(h) provides for one method of use to be examined with the elected compounds. A broad disclosure of utility as in the cited claims cannot be deemed in compliance with 35 USC 101 and 35 USC 112 first paragraph.

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The PTO has amended the guidelines to clarify “specific utility”. The court focused on the fact that the applicant failed to identify a “specific utility” in *Brenner vs Manson*.

This requirement of one specific utility is consistent with unity of Invention practice in International Applications and National Phase Applications under 35 USC 371 and PCT rule 13.2 for PCT applications.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Due to the distinct nature of the inventions a restriction is set forth in writing.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

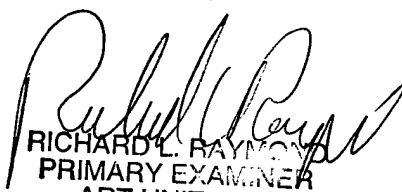
Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on weekdays from 8.30 AM to 5.00 PM.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

VB

V. Balasubramanian (Bala)


RICHARD L. RAYMOND
PRIMARY EXAMINER
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3/26/2001